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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,017	03/02/2004	Maik Obendorf	2877	1212

7590 12/13/2004

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,017	OBENDORF ET AL.	
	Examiner	Art Unit	
	Zachary C Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 14-18 drawn to a method of determining the effect of a test substance on ligand-induced activity of a nuclear receptor, classified in class 435, subclass 7.2.

II. Claims 12-13, drawn to a method of determining interference of a co-modulator mechanism by measuring concentrations of an androgen receptor and a Ewing sarcoma protein, classified in class 435, subclass 7.1.

III. Claims 19-20, in so far as they are drawn to a method of diagnosing illnesses brought about by dysfunction of a receptor comprising using a nucleic acid, classified in class 435, subclass 6.

IV. Claims 19-20, in so far as they are drawn to a method of diagnosing illnesses brought about by dysfunction of a receptor comprising using a antibody, classified in class 435, subclass 7.2.

V. Claim 21-22, in so far as they are drawn to a method of treatment of illnesses using gene therapy using SEQ ID NO: 1, classified in class 514, subclass 44.

VI. Claims 21-22, in so far as they are drawn to a method of treatment of illnesses using an anti-sense nucleic acid against SEQ ID NO: 1, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of an *test substance* that modulates a biological ligand-induced activity of a nuclear receptor, which is not required by any of the other Inventions. Invention II requires search and consideration of *interference of a co-modulator mechanism* which is not required by any of the other Inventions. Inventions III and IV require search and consideration of *diagnosis* of illnesses brought about by dysfunction of a receptor, which is not required by any of the other Inventions. Inventions V and VI require search and consideration of *treatment* of illnesses brought about by dysfunction of a receptor, which is not required by any of the other inventions.

Although Inventions III and IV are both drawn to diagnosis of illness brought about by dysfunction of a receptor, they are patentably distinct because Invention III is drawn to diagnosis using a nucleic acid and Invention IV is drawn to diagnosis using an antibody. Polynucleotides (composed of nucleic acids), and antibodies (polypeptides composed of amino acids) are structurally distinct molecules. Any relationship between a polynucleotide and a polypeptide depends on the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide used in Invention III will not encode the antibody used in Invention III, and the antibody used in Invention IV cannot be

encoded by a polynucleotide used in Invention III. Therefore, the polynucleotide and antibody are patentably distinct and have a separate status in the art as shown by their different classifications. Furthermore, there would be a serious search burden because a search of the polynucleotide used in Invention III would not be used to determine the patentability of an antibody used in Invention IV and vice-versa. Because the nucleic acid and antibody are patentably distinct, methods of using these compounds are also patentably distinct.

Although Inventions V and VI are both drawn to treatment of illness brought about by dysfunction of a receptor, they are patentably distinct because Invention V is drawn to treatment using a nucleic acid of SEQ ID NO: 1 and Invention VI is drawn to treatment using a molecule that is antisense to the nucleic acid of SEQ ID NO: 1. Although the sense and antisense molecules are both nucleic acids, these compounds are patentably distinct both because they are used in materially different processes which processes are completely different and distinct. The arts of antisense therapy (to inhibit protein production by nucleic acid interference) and sense gene therapy (to induce recombinant production of proteins) are separate and distinct, and require non-coextensive searches. Because the sense and antisense nucleic acids are patentably distinct, methods of using these compounds are also patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction Within Group I

If Group I is elected, further restriction with the elected group is required, as follows: one nuclear receptor selected from the group consisting of an androgen receptor, G-estrogen receptor, p-estrogen receptor, progesterone receptor, glucocorticoid receptor, mineralocodicoid receptor, thyroid gland hormone receptor, vitamin-D receptor, peroxisome proliferator-activated receptor, retinic acid receptor, retinoid-X receptor or a specific orphan receptor.

Although the classifications for nuclear receptors are overlapping, each represents a patentably distinct product, having different sequences and requiring separate sequence searches, and methods of using the proteins are also therefore patentably distinct.

Applicants are advised that this is not a species election.

Species Election

In addition to the above further restriction requirement, a further election of the following species is required as follows:

a) Applicant must elect one of the following patentably distinct species of cell type in the claimed invention: prostate cells, nerve cells, glia cells, fibroblasts, blood cells, osteoblasts, osteoclasts, hepatocyes, epithelial cells, or muscle cells.

b) Applicant must further elect one of the following patentably distinct species of methods of measuring: radio immunoassay, ELISA, immunodyeing, RT-PCR, Western Blot, or Northern Blot.

Each cell type is considered to constitute a patentably distinct species because they have separate structures, and require separate searches. Each measuring method is considered to constitute a patentably distinct species because the methods can be performed independently of each other, and require separate searches. Search of more than a single species of each type would constitute a burden on the Office.

Applicant is required under 35 U.S.C 121 to elect a) one type of cell and b) one type of measuring method for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6-7, and 10-22, are generic with regard to cell type and claims 1-12 and 14-22 are generic with regard to measuring methods.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Michael Striker on 12/7/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

EILEEN B. O'HARA
PATENT EXAMINER

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